Translation

PCT/JP2003/010090

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP03-0196-00	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/010090	International filing date (*day/month/year*) 07 August 2003 (07.08.2003)	Priority date (*day/month/year*) 28 August 2002 (28.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/221, 9/70, 47/12, 47/32, A61P 13/10		
Applicant HISAMITSU PHARMACEUTICAL CO., INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16 December 2003 (16.12.2003)	11 May 2004 (11.05.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7	YES
	Claims	1-6, 8-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Document 1: WO 02/38139 A1 (Hisamitsu Pharm. Co., Inc.), 16 May 2002

Document 2: WO 02/45699 A2 (LTS Lohmann Therapie-Systeme A. G.), 13 June 2002

Document 3: WO 95/31190 A1 (Hisamitsu Pharm. Co., Inc.), 23 November 1995

Document 4: JP 9-301854 A1 (Sekisui Chemical Co., Ltd.), 25 November 1997

Document 5: EP 913158 A1 (Permatec Tech A. G.), 05 June 1999

[1] The invention that is set forth in claims 1-6 and 8-10 lacks novelty and does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 discloses a "adhesive preparation that comprises a support and an adhesive layer configured from an adhesive base agent and oxybutynin..., which is disposed upon said support, wherein the aforementioned adhesive base agent comprises an elastomeric polymer and an acrylic polymer that contains substantially no carboxyl groups or hydroxy groups, and the weight ratio of the content of the aforementioned acrylic polymer to the content of the aforementioned elastomeric polymer is between 1 : 4 and

1 : 19" (Document 1 discloses the feature of adding oxybutynin as an active component on page 6 of the description; discloses the feature of adding an elastomeric polymer such as a styrene-isoprene-styrene block copolymer as the adhesive base agent on page 8 of the description; discloses the feature of adding an elastomeric polymer along with a (meth) acrylic polymer that comprises 2-ethylhexyl acrylate as the adhesive base agent on page 8 of the description; and discloses a feature wherein the content of the acrylic polymer is between 2 and 88% by weight on pages 8-9 of the description. Furthermore, refer to page 5 of the description and the examples with regards to the feature of adding carboxylic acid to the adhesive base agent.).

[2] The inventions that are set forth in claims 1-10 do not involve an inventive step in the light of document 1 and documents 2-5 cited in the international search report.

Refer to section [1], above.

Document 2 discloses an adhesive preparation that comprises a support and an adhesive layer configured from an adhesive base agent and a medicament, which is disposed upon said support, wherein the aforementioned adhesive base agent comprises an elastomeric polymer and an acrylic polymer that contains substantially no carboxyl groups or hydroxy groups, and the weight ratio of the content of the aforementioned acrylic polymer to the content of the aforementioned elastomeric polymer is between 1 : 4 and 1 : 19; and indicates that oxybutynin can be used as the medicament (refer to page 10).

Documents 3-5 indicate suitable adhesive base agents, mixture ratios and the like for use when configuring a percutaneous preparation that comprises a medicament such as oxybutynin; therefore, it would be easy

for a person skilled in the art to optimize such conditions with regards to the adhesive preparations that are disclosed in documents 1 and 2.

Furthermore, the inventions that are set forth in claims 1-10 cannot be considered to exhibit an effect that could not have been predicted in comparison to the adhesive preparations that are disclosed in document 1 and document 2.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*

see supplemental sheet

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: VI.1

WO 02/69942 A1 12 September 2002 07 March 2002 07 March 2001
(Hisamitsu Pharm. Co., Inc.)
[E, X]